IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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February 8, 2019

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 6, 2019. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Kalydeco (Ivacaftor); Orkambi (Lumicaftor/Ivacaftor); Hematopoietics/Chronic ITP; Elagolix (Orilissa); Oral Constipation Agents; and Desmopressin Acetate Nasal Spray (Noctiva). The DUR Commission members also discussed proposed ProDUR edits for duplicate antipsychotics in adults; concurrent therapy with CNS stimulants and atomoxetine; and age edits for CNS stimulants and atomoxetine. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a November 20, 2018 letter that was sent to them detailing the proposed criteria for Kalydeco (Ivacaftor); Orkambi (Lumicaftor/Ivacaftor); Hematopoietics/Chronic ITP; Elagolix (Orilissa); Oral Constipation Agents; and Desmopressin Acetate Nasal Spray (Noctiva) in addition to the proposed ProDUR edits for duplicate antipsychotics in adults; concurrent therapy with CNS stimulants and atomoxetine; and age edits for CNS stimulants and atomoxetine.

Kalydeco (Ivacaftor)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for Kalydeco™ (ivacaftor). Payment will be considered for patients when the following criteria are met:

1. Patient *meets the FDA approved age* ~~is 2 years of age or older~~; and
2. Has a diagnosis of cystic fibrosis; and
3. Patient has one of the CFTR gene mutations as indicated in the FDA approved label as detected by an FDA-cleared CF mutation test; and
4. Prescriber is a CF specialist or pulmonologist; and
5. Baseline liver function tests (AST/ALT) are provided.

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. Adherence to ivacaftor therapy is confirmed; and
2. Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.

Orkambi (Lumacaftor/Ivacaftor)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient *meets the FDA approved age* ~~is 6 years of age or older~~; and
2. Has a diagnosis of cystic fibrosis; and
3. Patient is homozygous for the *F508del* mutation in the *CFTR* gene as confirmed by a FDA-cleared CF mutation test; and
4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and
5. Prescriber is a CF specialist or pulmonologist.

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and
2. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

Hematopoietics/Chronic ITP (formerly Thrombopoietin Receptor Agonists)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
~~Payment~~ Prior authorization is required for *hematopoietics/chronic ITP agents* ~~a preferred thrombopoietin receptor agonist~~. *Request must adhere to all FDA approved labeling.* Payment for a non-preferred *hematopoietic/chronic ITP agent* ~~thrombopoietin receptor agonist~~ will be considered following documentation of a recent trial and therapy failure with a preferred *hematopoietic/chronic ITP agent* ~~thrombopoietin receptor agonist~~, when applicable, unless such a trial would be medically contraindicated*. Payment* will ~~only~~ be considered *under the following conditions*: ~~for cases in which there is~~

1. A diagnosis of *thrombocytopenia with* chronic immune *thrombocytopenia* ~~thrombocytopenic purpura~~ (ITP) (Promacta, Nplate, or Tavalisse)
    a. *Patient has* documentation of an insufficient response to a corticosteroid, ~~an~~ immunoglobulin, or ~~the patient has undergone a~~ splenectomy.
2. ~~Payment for eltrombopag (Promacta®) for the treatment of chronic hepatitis C associated thrombocytopenia will only be considered to allow for initiation and/or maintenance of interferon-based therapy with ribavirin when the patient has a baseline platelet count less than 75 x 10^9 L. Requests will not be considered under the following conditions:~~
    a. ~~Patient taking direct acting antiviral agents for the treatment of chronic hepatitis C genotype 1 infection in addition to interferon-based therapy with ribavirin.~~
    b. ~~Patients taking direct acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.~~
    c. ~~Patients with decompensated liver disease with a Child-Pugh score > 6 (Class B & C).~~

~~d. Patients with a history of ascites.~~
~~e. Patients with hepatic encephalopathy.~~

3. ~~Payment for eltrombopag (Promacta®) for the treatment~~ A *diagnosis* of severe aplastic anemia (Promacta) ~~will only be considered under the following conditions:~~
    a. Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and
    b. Patient has a platelet count less than or equal to 30 $x10^9$/L.
    c. If criteria for coverage are met, initial authorization will be given for 16 weeks. Documentation of hematologic response after 16 weeks of therapy will be required for further consideration.
4. *A diagnosis of thrombocytopenia with chronic liver disease in patients who are scheduled to undergo a procedure (Mulpleta)*
    a. *Patient has a platelet count less than 50 x 10^9/L; and*
    b. *Dosing will begin 8 to 14 days prior to a scheduled procedure; and*
    c. *Patient is scheduled to undergo a procedure within 2 to 8 days after the last dose; and*
    d. *A platelet count will be obtained no more than 2 days before starting treatment.*

Elagolix (Orilissa)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for gonadotropin-releasing hormone (GnRH) antagonists. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
2. Pregnancy has been ruled out; and
3. Patient does not have osteoporosis; and
4. Patient does not have severe hepatic impairment; and
5. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine and gemfibrozil); and
6. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and
7. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
8. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose.

Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Oral Constipation Agents

Proposed Clinical Prior Authorization (changes italicized/highlighted/stricken)

Prior authorization is required for oral constipation agents *subject to clinical criteria*. *Payment for non-preferred oral constipation agents will be considered only for cases in which there is*

documentation of a previous trial and therapy failure with a preferred oral constipation agent.
Payment will be considered under the following conditions:

1. Patient *meets the FDA approved age* ~~is 18 years of age or older~~; and
2. Patient must have documentation of adequate trials and therapy failures with both of the following:
    a. Stimulant laxative (senna) plus saline laxative (milk of magnesia); and
    b. Stimulant laxative (senna) plus osmotic laxative (polyethylene glycol or lactulose); and
3. Patient does not have a known or suspected mechanical gastrointestinal obstruction; and
4. Patient has one of the following diagnoses:
    a. A diagnosis of chronic idiopathic constipation (Amitiza®, Linzess™, Trulance®)
        i. Patient has less than 3 spontaneous bowel movements (SBMs) per week; and
        ii. Patient has two or more of the following symptoms within the last 3 months:
            1. Straining during at least 25% of bowel movements;
            2. Lumpy or hard stools for at least 25% of bowel movements; and
            3. Sensation of incomplete evacuation for at least 25% of bowel movements; and
        iii. Documentation the patient is not currently taking constipation causing therapies
    b. A diagnosis of irritable bowel syndrome with constipation (Amitiza®, Linzess™, Trulance®)
        i. Patient is female (Amitiza® only); and
        ii. Patient has *recurrent* abdominal pain ~~or discomfort at least 3~~ *on average at least 1* day~~s~~ per *week* ~~month~~ in the last 3 months associated with two (2) or more of the following:
            1. ~~Improvement with~~ *Related to* defecation;
            2. ~~Onset~~ Associated with a change in stool frequency; and/or
            3. ~~Onset~~ Associated with a change in stool form
    c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™, Relistor®, or Symproic®)
        i. Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and
        ii. Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:
            1. Hard to very hard stool consistency;
            2. Moderate to very severe straining; and/or
            3. Having a sensation of incomplete evacuation
        ~~iii. Patient has documentation of an adequate trial and therapy failure with Amitiza®, if prior authorization request is for a different oral constipation agent.~~

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

Desmopressin Acetate (Noctiva)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Noctiva (desmopressin acetate). Payment will be considered for patients when the following criteria are met:

1. Patient is 50 years of age or older; and
2. Patient has a diagnosis of nocturnal polyuria as confirmed by a 24-hour collection which notes the presence of greater than 33% of 24-hour urine production occurring at night; and
3. Patient wakens at least 2 times at night to void; and
4. Patient has attempted fluid restriction in the evenings without improvement in nocturnal polyuria; and
5. Patient is not taking a diuretic in the evening; and
6. Patient does not have any of the following contraindications:
    a) Current or previous history of hyponatremia; and
    b) Primary nocturnal enuresis; and
    c) Polydipsia; and
    d) Concomitant use with loop diuretics, systemic or inhaled glucocorticoids; and
    e) Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion; and
    f) Estimated glomerular filtration rate < 50 mL/min/1.73 m^2; and
    g) Illnesses that can cause fluid or electrolyte imbalance; and
    h) New York Heart Association (NYHA) Class II-IV congestive heart failure; and
    i) Uncontrolled hypertension.

Initial requests will be considered for 3 months. Requests for continuation of therapy will require the following:

1. Patient continues to meet above criteria; and
2. Patient has experienced a decrease in nocturnal voiding; and
3. There is no evidence of toxicity (e.g., hyponatremia, fluid retention, or electrolyte imbalances).

ProDUR Recommendations

- Antipsychotics in Adults – Duplicate Therapy
    - ProDUR edit to limit members 18 years of age and older to two chemically distinct antipsychotics.
- CNS Stimulants and Atomoxetine – Concurrent Therapy
    - For members under 21 years of age, allow one unit of a short-acting stimulant with a long-acting stimulant by implementing a quantity limit on all short-acting stimulants to one unit per day (i.e., 30 units per 30 days). The intent is to require the use of long-acting stimulants, while allowing for one dose of a short-acting stimulant if needed.
- CNS Stimulants and Atomoxetine – Age Edit

Medication	**Drug Name***	**Minimum FDA Approved Age**
Amphetamines	Adderall Adzenys XR ODT Desoxyn Dexedrine	3 years of age

	Dynavel XR Evekeo Mydayis Vyvanse	
	Adderall XR Dexedrine ER	6 years of age
Dexmethylphenidate	Focalin Focalin XR	6 years of age
Methylphenidate	Aptensio XR Concerta Cotempla XR ODT Daytrana Metadate CD Methylin QuilliChew Quillivant XR Ritalin IR/LA/SR	6 years of age
Atomoxetine	Strattera	6 years of age

* ProDUR age edit would apply to brand and generic

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Kalydeco (Ivacaftor); Orkambi (Lumicaftor/Ivacaftor); Hematopoietics/Chronic ITP; Elagolix (Orilissa); Oral Constipation Agents; and Desmopressin Acetate Nasal Spray (Noctiva) in addition to the proposed ProDUR edits for duplicate antipsychotics in adults; concurrent therapy with CNS stimulants and atomoxetine; and age edits for CNS stimulants and atomoxetine.

Sincerely,

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